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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/008,430 | 11/13/2001 | Matthew F. Ogle | 1416.10US01 | 3022 |

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| EXAMINER | |
|---|---|
| LANKFORD JR, LEON B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/008,430 | OGLE ET AL. | |
| | Examiner | Art Unit | |
| | Leon Lankford | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/23/04 has been entered.

Applicant's arguments filed 7/23/2004 have been fully considered but they are not persuasive. The rejections remain for the reasons of record.

Applicant argues that the factors taught by Caryle and Keogh don't meet their definition of a "stimulation compound" however "stimulation compound" is not defined in the specification in such a way to exclude the compounds taught in the prior art. For example, many growth factors are known to stimulate the production of other growth factors either directly or indirectly thus meeting applicant's proposed definition.

Confusingly, applicant argues that agonists are not stimulation compounds yet claims a known VEGF agonist, HIF, as a stimulation factor.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 & 7-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant generically claims a "stimulation compound" or a polypeptide stimulation compound" however the specification does not contain an adequate description for the entire scope of this terms and thus the claims. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Caryle et al(99/37337).

Carlyle teaches a substrate, e.g. a prothesis, on which is coated VEGF or related factors. The factors are attached via chemical bonding, crosslinking or an adhesive. The reference anticipates the claim subject matter.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Keogh (6033719).

Keogh teaches a device on which is coated a biomolecule factor through covalent bonds. The reference anticipates the claim subject matter.

Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Keogh (6033719).

Keogh teaches a device on which is coated a biomolecule factor through covalent bonds. The reference anticipates the claim subject matter.

Claims 1-2, 7, 23-24, 26, 28, 31-33 & 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al(WO 98/20027).

Martin teaches a device onto or into which a VGEF agonsit is attached (see eg the claims). The reference anticipates the claims.

Claims 31-33 are rejected under 35 U.S.C. 102(a) as being anticipated by Slaikeu et al(WO 01/03607).

Slaikeu teaches a medical device on which is coated or associated an angiogenic factor. The reference anticipates the claim subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the

inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlyle et al(99/37337) in view of Martin et al(WO 98/20027).

Carlyle teaches a medical device on to which VEGF has been attached to to promote population of the device with viable cells and other positive results. Carlyle teaches all of the claimed devices in detail through the reference and also details means for attaching the peptide to the device in all the methods applicant claims. The reference teaches all of the claimed limitations except that the reference uses VEGF and does not teach using a VEGF stimulation compound however at the time the invention was made it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a VEGF stimulation compound for the VEGF used by Carlyle because Martin teaches that using such compounds produces like results to using the peptide itself. The references clearly provide a reasonable expectation of success that using a known stimulator/agonist of VEGF on a medical device would produce the same desired results as sought by Carlyle.

As the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed device are result effective

variables, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references.

Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlyle et al(99/37337) in view of Martin et al(WO 98/20027) and further in view of Semenza et al(6124131) or Tsuzuki et al(Cancer Research. 60. 2000).

The teachings of Carlyle and Martin are set forth above.

Neither Carlyle nor Martin specifically teaches using HIF-1α as the stimulator/agonist of VEGF, however it would have been obvious at the time the invention was made to use HIF-1α as the agonist as taught by Martin in the process of Carlyle because Semenza and Tsuzuki teach that HIF-1α is a known agonist of VEGF. There was a reasonable expectation that substituting HIF-1α for the VEGF in the invention of Carlyle would produce like results.

Accordingly, the claimed invention was prima facie obvious to one of ordinary

skill in the art at the time the invention was made especially in the absence of evidence

to the contrary.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply

is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to L Blaine Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

L. Blaine Lankford
Primary Examiner
Art Unit 1651

LBL